INSTRUCTIONS FOR USE

MORCHER® Capsular Tension Rings

Manufacturer: Morcher GmbH
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Germany

Description:
The MORCHER® Capsular Tension Ring is a sterile, non-optical ocular implant, manufactured from a single piece of PMMA (Polymethylmethacrylate).

Indications for Use:
For the stabilization of the crystalline lens capsule in the presence of weak or partially absent zonules in adult patients undergoing cataract extraction with intraocular lens implantation. Conditions associated with weak or partially absent zonules may include primary zonular weakness (*e.g.*, Marfan's Syndrome), secondary zonular weakness (*e.g.*, trauma or vitrectomy), cases of zonulysis, cases of pseudoexfoliation and cases of Marchesani's Syndrome.

Contraindications:

The Capsular Tension Ring should not be used in children 12 years of age or younger since this device is contraindicated in eyes still growing.

The MORCHER® Capsular Tension Ring is contraindicated for patients with perforated or damaged capsules.

Warnings:

The effect of the Capsular Tension Ring on the progression of zonular instability over time is unknown at this date.

Eyes with pseudoexfoliation syndrome and decreased anterior chamber depth exhibit a greater likelihood of zonular instability at the time of surgery and an increased probability of intraoperative complications.

Since the number of eyes with zonular dehiscence greater than 50% was very low (13/316, 4%) in this study, no scientific conclusions can be drawn regarding the probable visual outcome in this population, especially in the presence of other preoperative pathologies. The physician should use his/her own discretion in utilizing the MORCHER capsular tension rings in these cases.

Precautions:

Do not use the MORCHER® Capsular Tension Ring if the packaging is damaged.

Do not use the MORCHER® Capsular Tension Ring if the sterile pouch is damaged or open.

Do not resterilize any MORCHER® Capsular Tension Ring.

Use only sterile buffered saline solution or its equivalent to rinse the implant

The implants are single use only and may not be reused.

The implants must be inspected before use, and any damaged implants should be returned to the manufacturer. Use only undamaged implants.

The implanting surgeon should be experienced and/or should have assisted in the implantation of a capsular tension ring, and should have successfully completed the associated training before attempting implantation of a capsular tension ring.

Outcome Analysis of Clinical Study:

A total of 316 eyes of 268 subjects were evaluated in the Core Phase I and Core Phase II clinical studies.

Table 1: Percentage of Zonular Dehiscence at Operation (n=316)

Zonular Dehiscence at Operation	n (%)
0%	109/316 (34.5%)
> 0 – 25%	77/316 (24.4%)
> 25% – 50%	29/316 (9.2%)
> 50% - 75%	8/316 (2.5%)
> 75% - 100%	5/316 (1.6%)
Unknown	88/316 (27.8%)
Total	**316/316 (100%)**

Table 1 shows the percentage of zonular dehiscence at the time of operation. Of the 316 study eyes, 34.5% had no zonular dehiscence, 24.4% had up to 25% dehiscence, and 9.2% had > 25% to 50% dehiscence.

Last corrected visual acuity at 10-14 weeks or later was stratified by the percentage of zonular dehiscence at surgery (Table 2) and by preoperative pathology (Table 3).

Table 2: Last Corrected Visual Acuity at 10-14 Weeks or Later Stratified by Zonular Dehiscence at Surgery

Percentage Zonular Dehiscence at Operation	Corrected Visual Acuity*	
	20/40 or Better n/N (%)**	Worse than 20/40 n/N (%)**
0%	92/104 (88.5%)	12/104 (11.5%)
> 0 – 25%	60/73 (82.2%)	13/73 (17.8%)
> 25% – 50%	21/27 (77.8%)	6/27 (22.2%)
> 50% - 75%	4/7 (57.1%)	3/7 (42.9%)
> 75% - 100%	4/4 (100%)	
Unknown	72/83 (86.7%)	11/83 (13.3%)

* If an eye had an uncorrected VA of 20/40 or better and the corrected VA was not reported, it was assumed that the corresponding corrected VA was 20/40 or better.
** n=number of eyes reported with the corresponding visual acuity in each zonular dehiscence group; N=number of eyes reported with a non-missing visual acuity in each zonular dehiscence group

Corrected visual acuity of 20/40 or better was reported for 84.8% of eyes (173/204) with zonular dehiscence of no more than 50% at operation.

Table 3: Last Corrected Visual Acuity at 10-14 Weeks or Later Stratified by Preoperative Pathology

Preoperative Pathology	Corrected Visual Acuity*	
	20/40 or Better n/N (%)**	Worse than 20/40 n/N (%)**
Pseudoexfoliation	81/92 (88.0%)	11/92 (12.0%)
Glaucoma	40/49 (81.6%)	9/49 (18.4%)
Previous filtering surgery	11/12 (91.7%)	1/12 (8.3%)
Poor pupil dilation	18/21 (85.7%)	3/21 (14.3%)
History of uveitis	1/2 (50.0%)	1/2 (50.0%)
Previous retinal detachment	6/13 (46.2%)	7/13 (53.8%)
Diabetic retinopathy	3/6 (50.0%)	3/6 (50.0%)
Macular degeneration	17/31 (54.8%)	14/31 (45.2%)
Amblyopia	4/5 (80.0%)	1/5 (20.0%)
Other	109/136 (80.1%)	27/136 (19.9%)
With any preoperative pathology	187/224 (83.5%)	37/224 (16.5%)
Without any preoperative pathol.	66/74 (89.2%)	8/74 (10.8%)

* If an eye had an uncorrected VA of 20/40 or better and the corrected VA was not reported, it was assumed that the corresponding corrected VA was 20/40 or better.
** n=number of eyes reported with the corresponding visual acuity in each preoperative pathology category; N=number of eyes reported with a non-missing visual acuity in each preoperative pathology category

Of the 316 implanted eyes, 224 (70.9%) presented with a history of pre-existing pathology and 74 (23.4%) had no pre-existing pathology. Close to 90% of eyes without preoperative pathology had a best corrected acuity of 20/40 or better, while a slightly lower proportion of eyes (83.5%) with pre-existing pathology had best corrected acuity of 20/40 or better. These data suggest that the existence of preoperative pathology was associated with worse post-operative outcome as measured by best-corrected acuity. As anticipated, pre-existing retinal disorders (e.g., retinal detachment, diabetic retinopathy, and macular degeneration) were significant contributors to poor postoperative outcomes.

Adverse Events:
Cumulative adverse events, i.e., total events occurring over the course of the clinical study, are reported for the full cohort of 316 eyes of 268 subjects; persistent adverse events, defined as adverse events that were present at one year or later are reported for 284 eyes of 241 subjects, since 27 subjects did not have an examination at 12 months or later. Persistent and cumulative adverse events occurring with an incidence of 1% or more are shown in Table 4.

The most frequently reported cumulative adverse events occurred during the first two weeks following surgery and consisted of anterior chamber inflammation (147/316; 46.5%), corneal edema (76/316, 24.1%), and striae (61/316, 19.3%). Other cumulative adverse events that occurred with a frequency of more than 5% were posterior capsular opacification (41/316;

13.0%), macular degeneration (40/316; 12.7%), elevated intraocular pressure (34/316; 10.8%), IOL decentration (29/316, 9.2%) and optic atrophy (17/316, 5.4%). The remaining cumulative events occurred at a frequency of less than 5%.

The most prevalent persistent adverse event was macular degeneration (25/284; 8.8%), followed by posterior capsular opacification (23/284; 8.1%), and IOL decentration (20/284; 7.0%). Persistent adverse events occurring at a rate of 1% to 2% included optic atrophy, retina detachment, deposits on IOL, cystoid macular edema and iritis. The remaining persistent adverse events occurred at frequencies of less than 1%.

Note: Decentration rates may be higher than reflected, since no consistent information is available whether centration data was obtained under dilated conditions or not.

Table 4: Persistent and Cumulative Adverse Event And Complications Sorted By Persistent Incidence Rate

Adverse Event & Complications	Persistent* 284 Eyes of 241 Subjects n/N (%)	Cumulative† 316 Eyes of 268 Subjects n/N (%)
Macular degeneration	25/284 (8.8%)	40/316 (12.7%)
Posterior capsular opacity	23/284 (8.1%)	41/316 (13.0%)
IOL decentered	20/284 (7.0%)	29/316 (9.2%)
Elevated IOP	14/284 (4.9%)	56/316 (17.7%)
Optic atrophy	6/284 (2.1%)	17/316 (5.4%)
Retinal detachment‡	6/284 (2.1%)	6/316 (1.9%)
Deposits on IOL	4/284 (1.4%)	12/316 (3.8%)
Iritis	3/284 (1.1%)	8/316 (2.5%)
Cystoid macular edema	3/284 (1.1%)	7/316 (2.2%)
Posterior synechiae	2/284 (0.7%)	5/316 (1.6%)
Blepharitis	2/284 (0.7%)	3/316 (0.9%)
Retinal pigment epithelium	2/284 (0.7%)	2/316 (0.6%)
Glaucoma	1/284 (0.4%)	6/316 (1.9%)
Corneal edema	1/284 (0.4%)	4/316 (1.3%)
Iridodonesis	1/284 (0.4%)	4/316 (1.3%)
Striae	1/284 (0.4%)	4/316 (1.3%)
AC inflammation (1 day to 2 weeks postop)		147/316 (46.5%)
Cortical remnants		8/316 (2.5%)
Vitreous problems		8/316 (2.5%)
Drusen		7/316 (2.2%)
Fibrin in pupil		4/316 (1.3%)

Directions for Use:
The Capsular Tension Ring can be implanted with the aid of forceps or an injector. The procedure involves slowly "dialing in" the ring through the capsulorhexis into the capsular bag. Smooth blade forceps may be used to gently insert the ring, which due to its shape will tend to follow the natural curve of the capsular bag. A hook (Sinskey type) may be helpful in the trailing eyelet of the ring to achieve the final insertion and placement in the capsule.

Note: Improper handling can result in the perforation of the capsule.

The physician should discuss the indications, contraindications, warnings, precautions, treatment responses, adverse events and procedure with the patient prior to the implant of a MORCHER® Capsular Tension Ring

Treatment with MORCHER® Capsular Tension Ring:
A complete ophthalmic history and assessment must be performed to determine the patient's eligibility for implantation of a Capsular Tension Ring. Please complete the Capsular Tension Ring implantation identification card for each treatment and return to the addressee printed on the card.

Implantation and Removal Procedure:
Selection of the proper Capsular Tension Ring size:
The anatomy of the eye, specifically the bulbus length, must be taken into account in the selection of the proper Capsular Tension Ring size.

Table 5: Sizes

Type	expanded	compressible	Bulbus length
14	12.3mm	To 10.0mm	< 24 – 28mm
14A	14.5mm	To 12.0mm	> 28mm
14C	13.0mm	To 11.0mm	24 – 28mm

Other Rings: See data on package labeling or on datasheet

Note: Capsular Ring Type 14A has a greater cross-sectional dimension than either the Type 14 or 14C, thereby providing a rigid design which may be useful to counteract the capsule's strong tendency to shrink in highly myopic eyes (approx. 28 mm or longer axial length). In such cases, we recommend implantation of a Capsular Tension Ring in combination with a security stitch. After insertion of 4/5 of the circumference of the ring into the capsular bag, a 10.0 nylon suture is threaded through the remaining eyelet. This will allow the end of the ring to be manipulated in combination with a notched hook in the chamber if there is a need to do so.

Opening the package and removing the Capsular Tension Ring:
Open the clear plastic pouch at the designated points and remove the primary container. Under aseptic conditions, carefully pull the seal off the container then, using smooth-tipped forceps, gently remove the Capsular Tension Ring from the container. Do not pull the ring.

Note: It is recommended to rinse the MORCHER® Capsular Tension Ring in sterile Ringer solutions or BSS® prior to implantation.

For manual use:
After removing the ring from the package, dial the ring through the incision (> 1mm) and the capsulorhexis into the capsular bag with a holding forceps.

Note: It is recommended to fill the capsular bag beforehand with a viscoelastic to prevent the anterior and posterior capsule from sticking to one another, thus making easier to slide the ring into the capsular bag.

For use with the injector:
(Injector G-32960 made by Geuder® AG, Heidelberg, Germany has been designed for clockwise one-hand implantation of the MORCHER® Capsular Tension Ring).

1. Engage the left eyelet of the capsular tension ring with the hook of the injector.

2. Slowly withdraw the capsular tension ring into the injector's tubing.

Note: For the implantation of the Capsular Tension Ring the guiding eyelet can remain exposed or be completely withdrawn into the tubing.

Note: When loading the injector, withdraw the ring into the injector's tube slowly in order to prevent any damage to the trailing eyelet when it comes in contact with the end of the tube.

3. Perform the implantation in a clockwise fashion.

Note: Follow the injector manufacturer's instructions to avoid problems and damage to the ring.

Removal of the Capsular Tension Ring
The ring is designed to stay in the eye for a lifetime. However, it is sometimes difficult to implant the Capsular Tension Ring satisfactorily into the bag on the first try and removal may be necessary. If it becomes necessary to remove the ring from the capsule at any time, it is recommended to use a hook to lift one end of the ring out of the capsulorhexis and redial the ring out of the bag. In some situations it may be desirable to cut the ring into two pieces with vannas scissors and to dial each piece separately out of the bag.

Sterilization and Delivery:
MORCHER® Capsular Tension Rings are sterilized by gamma radiation. They are supplied in germproof, sealed containers that are, in turn, packed in sterile pouches (sterile double packaging).

Storage Directions:

- store flat
- keep away from sunlight
- do not expose to extreme temperatures
- keep dry

Adverse Reaction Reporting:
Adverse reactions and/or potentially sight-threatening complications that may reasonably regarded as ring related and that were not previously expected in nature, severity or degree of incidence, should be reported to Morcher GmbH. This information is being requested from all surgeons in order to document potential long-term effects of ring implantation. To report such adverse reactions/complications, contact the Morcher Quality Assurance Department at:

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Caution: **Federal Law (U.S.) restricts this device to sale or use by or on the order of a physician.**